

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K-993068

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|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Submitter name, address, contact | Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-4041

Contact Person: Marlene Shulman |
| 2. Preparation date | Date Special 510(k) prepared: 10 September 1999 |
| 3. Device name | Trade or Proprietary Name:
VITROS Immunodiagnostic Products CK-MB Reagent Pack
VITROS Immunodiagnostic Products CK-MB Calibrators

Common Name : CK-MB assay
Classification Name: Creatine phosphokinase/ creatine kinase or isoenzymes test system |
| 4. Predicate device | The VITROS Immunodiagnostic Products CK-MB Reagent Pack for use with human serum and plasma (EDTA or heparin) and VITROS Immunodiagnostic Products CK-MB Calibrators are substantially equivalent to the VITROS Immunodiagnostic Products CK-MB Reagent Pack for use with human serum and VITROS Immunodiagnostic Products CK-MB Calibrators. |

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510(k) Summary, Continued

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- 5. Device description** The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum and plasma. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products range of immunoassay products (in this case VITROS Immunodiagnostic Products CK-MB Reagent Pack, VITROS Immunodiagnostic Products CK-MB Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS CK-MB assay, and VITROS Immunodiagnostic Products High Sample Diluent B).
Note: High Sample Diluent B was cleared as part of the VITROS Immunodiagnostic Products Total β -hCG Reagent Pack and VITROS Immunodiagnostic Products Total β -hCG Calibrators 510(k) premarket notification (K970894).
2. The VITROS Immunodiagnostic System – instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).
3. Common reagents used by the VITROS System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).

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510(k) Summary, Continued

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| 5. Device description,
Continued | The VITROS System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products. |
| 6. Device intended use | The VITROS CK-MB assay is intended for the <i>in vitro</i> quantitative measurement of CK-MB in human serum or plasma (EDTA or heparin). |
| 7. Comparison to predicate device | <p>The VITROS Immunodiagnostic Products CK-MB Reagent Pack for use with human serum and plasma (EDTA or heparin) and VITROS Immunodiagnostic Products CK-MB Calibrators are substantially equivalent to VITROS Immunodiagnostic Products CK-MB Reagent Pack for use with human serum which was cleared by the FDA (K973030) for IVD use.</p> <p>Table 1 lists the characteristics of the assays performed using the VITROS CK-MB assay for use with human serum and plasma (EDTA or heparin) and the VITROS CK-MB assay for use with human serum.</p> |
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510(k) Summary, Continued

7. **Comparison to predicate device,**
Continued

Table 1

Device Characteristic	VITROS CK-MB assay for use with human serum and plasma (EDTA or heparin)	VITROS CK-MB assay for use with human serum
Calibration range	0-400 ng/mL	0-400 ng/mL
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Antibody	Mouse monoclonal anti-CK-BB antibody (Biotinylated antibody reagent). Mouse monoclonal anti-CK-MB antibody (HRP-Conjugate reagent).	Mouse monoclonal anti-CK-BB antibody (Biotinylated antibody reagent). Mouse monoclonal anti-CK-MB antibody (HRP-Conjugate reagent)
Instrumentation	VITROS Immunodiagnostic System	VITROS Immunodiagnostic System
Sample type	Serum and plasma (EDTA or heparin).	Serum
Sample volume	40µL	40µL
Incubation time and temperature	16 minutes at 37°C with shaking	16 minutes at 37°C with shaking

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510(k) Summary, Continued

- 8. Conclusions** The data presented in the pre-market notification demonstrate that the performance of the VITROS CK-MB assay for use with human serum and plasma (EDTA or heparin) is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using currently commercially available reagents along with patient samples covering a variety of clinical categories.

The data presented in the premarket notification provide a reasonable assurance that the VITROS CK-MB assay for use with human serum and plasma (EDTA or heparin) is safe and effective for the stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 4 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Marlene A. Shulman
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K993068
Trade Name: VITROS Immunodiagnostic Products CK-MB Reagent Pack
VITROS Immunodiagnostic Products CK-MB Calibrators
Regulatory Class: II
Product Code: JHX, JIS
Dated: September 10, 1999
Received: September 13, 1999

Dear Ms. Shulman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

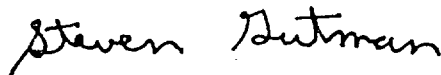
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

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510(k) Number (if known):

K 993068


Device Name:

VITROS Immunodiagnostic Products CK-MB Reagent Pack
VITROS Immunodiagnostic Products CK-MB Calibrators

Indications for Use:

VITROS CK-MB Reagent Pack - Creatine phosphokinase/creatinine kinase or isoenzymes test systems is a device intended to measure the enzyme creatine phosphokinase or its isoenzymes in serum and plasma in the diagnosis and treatment of myocardial infarction.

VITROS CK-MB Calibrators - For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of CK-MB in human serum and plasma.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 993068

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Ortho-Clinical Diagnostics VITROS Immunodiagnostic Products CK-MB Reagent Pack -
VITROS Immunodiagnostic Products CK-MB Calibrators